Paralyzed Veterans of America

consortium for SPINAL CORD MEDICINE
CLINICAL PRACTICE GUIDELINES

CONSUMER GUIDE: EAW

Exoskeleton Assisted Walking (EAW): What You Should Know

A Guide for People with Spinal Cord Injury

Mount Sinai
Rehabilitation & Human Performance

Supported in full by Grant 870 from
Paralyzed Veterans of America
Education Foundation

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CONSUMER GUIDE:

EXOSKELETON ASSISTED WALKING (EAW) for Persons with Spinal Cord Injury

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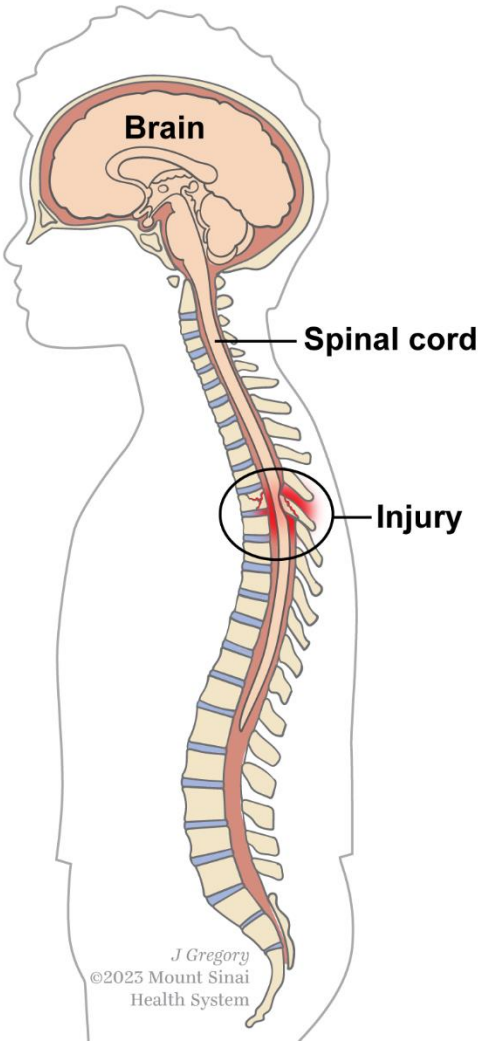
Introduction



Following a spinal cord injury (SCI), people commonly have difficulties standing and walking. A person with a SCI who is eligible can use a robotic exoskeleton to assist with standing and walking in the home and in the community. This consumer guide will help you understand what an exoskeleton-assisted walking (EAW) device is and if you are a candidate to use one.

These guidelines and topics should be discussed with your medical provider or health care team. Although exoskeletons can be used for several conditions, this consumer guide is intended for individuals with spinal cord injury.

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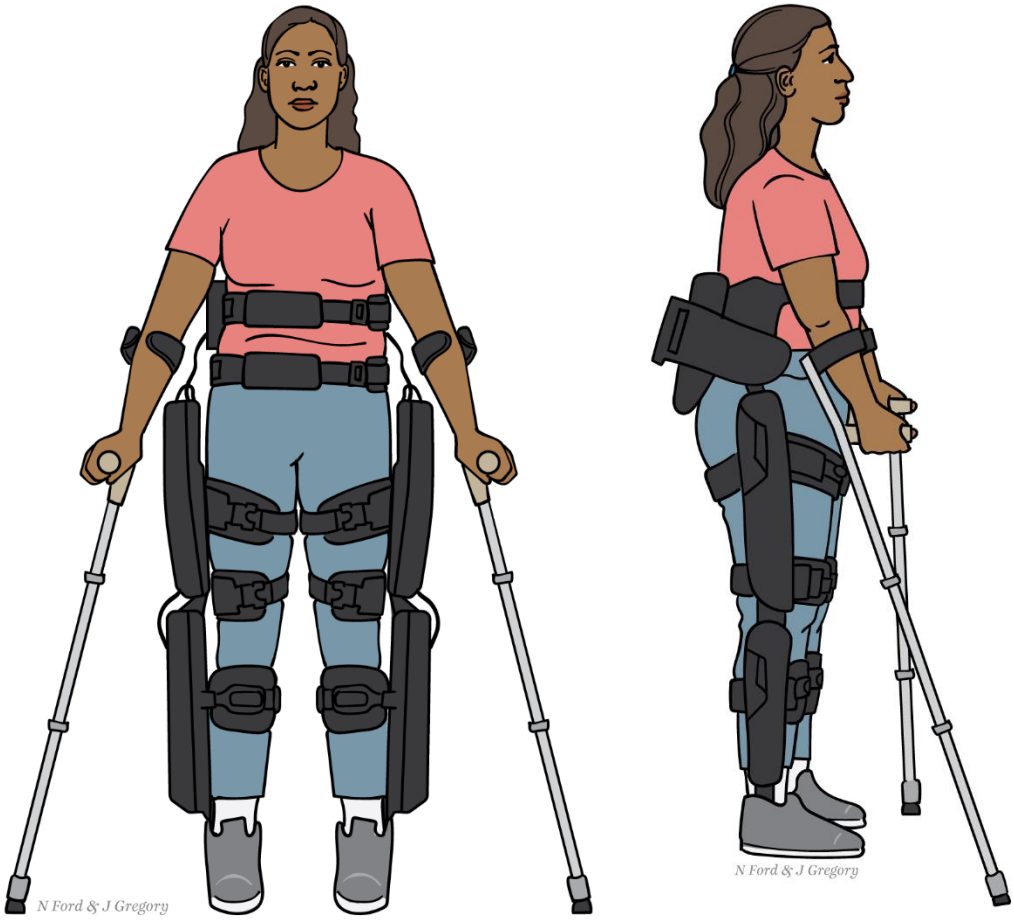
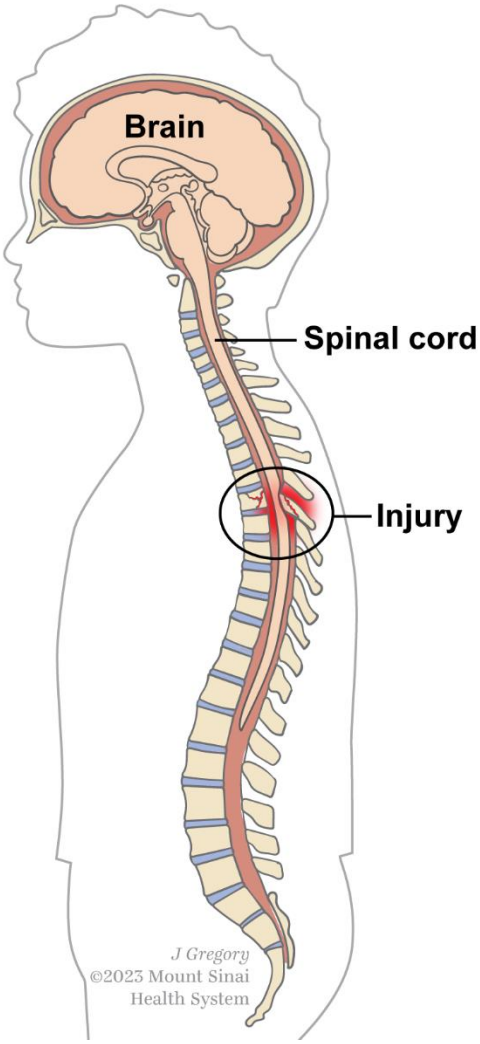
What is an exoskeleton?



- An exoskeleton is a wearable robotic device that uses an external frame for upright support, with movement driven by computers and sensors.
- A powered exoskeleton has external frames around the pelvic area, on the upper and lower legs, and motors at the hips, knees, and/or ankles that help people stand and walk.
- Walking in an exoskeleton can be accomplished with an assistive device such as a walker or crutches and with or without physical assistance from a companion.
- Coordination of sit-to-stand, stand-to-sit, and walking is triggered by weight shifting.

Who can use an exoskeleton?



- People who have difficulties walking due to injuries including:
  - Spinal Cord Injury
  - Stroke
  - Brain Injury
  - Multiple Sclerosis

- This guide is focused on people with Spinal Cord Injury but other people with walking difficulties may also benefit from use.

- For more information regarding FDA (Food and Drug Administration) approved exoskeleton devices please visit:
  - https://exoskeletonreport.com/2023/03/intended-use-of-the-11-fda-approved-medical-exoskeletons-in-2023/#respond

See user testimonies below to find out the perspectives of exoskeleton users:

- Ekso/Indego- https://eksobionics.com/customer-stories/#
- ReWalk - https://youtube.com/playlist?list=PLgp_VphhkIqitPEQLg4vSNUThHV6FkoRN

What exoskeleton devices are currently approved for Spinal Cord Injury?

- As of **June 1st, 2023,** these are the current devices that have been approved for market in the United States by the Food and Drug Administration (FDA):

EksoNR **EksoGT**

https://eksobionics.com/eksonr/

Indego

https://eksobionics.com/indego/

ReWalk 6.0

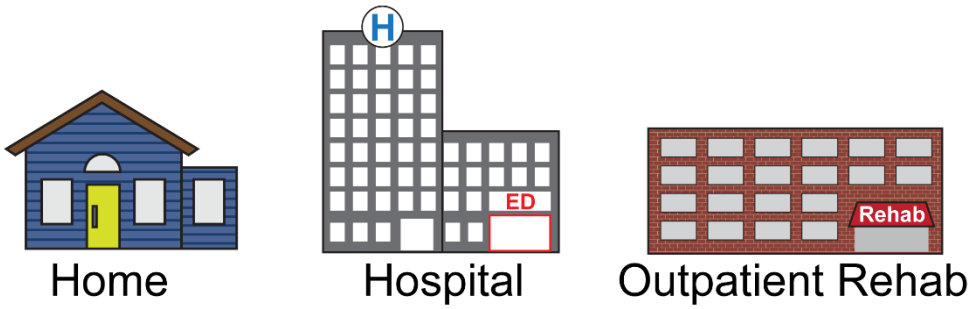
https://rewalk.com/rewalk-personal-3/

	EksoNR and Ekso GT	Indego	ReWalk P6.0
Rehabilitation Institute Use	C7 to L5*	C7 to L5*	T4 to T6*
Personal Use (Home)	Not allowed	T3 to L5*	T7 to L5*
Height requirements	5’2” – 6’2” (158 – 188 cm)	5'1" – 6'3" (155 – 191 cm)	5’3” – 6’2” (160 – 190 cm)
Max Weight requirements	220 lb (100kg)	250 lb (113 kg)	220 lb (100 kg)
Device Weight	50 lb (23 kg)	29 lb (13 kg)	66 lb (30 kg)

*For more details and information about exoskeletons, please see Appendix A

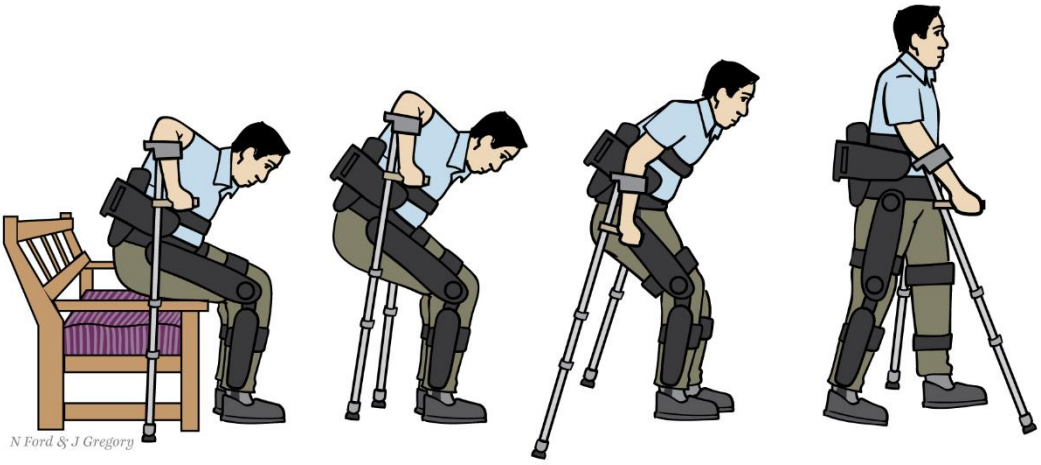
- Exo Atlet and Phoenix are recently approved exoskeletons for SCI, however there is limited knowledge and experience of these devices at this time.

When can I use an exoskeleton?



- In some cases, newly injured people can be evaluated by a physician and may be eligible to begin using an EAW device during their acute in-patient rehabilitation by a certified trainer.
- Generally, most users begin using them after completing acute rehabilitation during outpatient rehabilitation.
- Depending on the model, exoskeletons may be used at home with a companion or at an institution with a certified trainer.

What types of activities can I perform with an exoskeleton?



- Examples of activities that can be performed with exoskeletons include:
    - Standing up
    - Sitting down
    - Stepping and walking short distances
    - Turning
    - Stopping
    - Mild slopes
    - Stairs **(Approved for ReWalk)**
    - Curbs **(Approved for ReWalk)**
    - Countertop Work
    - Reaching Overhead Cabinets
- Exoskeletons can be used indoors or on outdoor surfaces and suggested to be used on open and even surfaces.
- Situations to avoid when using the device:
    - Wet Floors
    - Any uneven surface the prevents clearing of the foot when stepping (Ex: Sand, floor filled with obstacles)
    - Potentially other surfaces yet to be identified
- Situations in which you may want to use the device:
    - Personal activity/ exercise
    - Social events

    - Assistance with activities of daily living
- See websites below for examples of what activities you may be able to perform:
    - Ekso
        - https://youtu.be/_7IcuqefNOQ
    - Indego
        - https://youtu.be/mJa4y7KrQvE
        - https://youtu.be/8TX2Xnqsbhs
    - ReWalk
        - https://www.youtube.com/playlist?list=PLqp_VphhkIqidHlGK1Rp2ik_QboW9NJED

Ekso

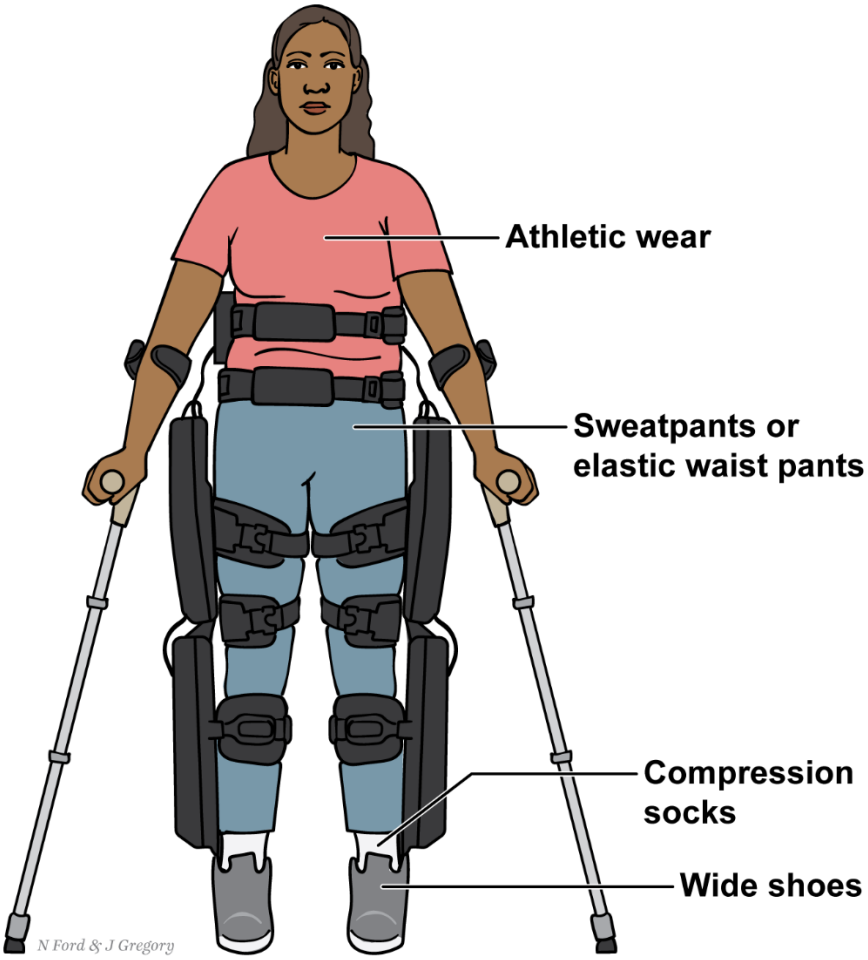
Indego

ReWalk 6.0

How long does it take to learn to use an exoskeleton?

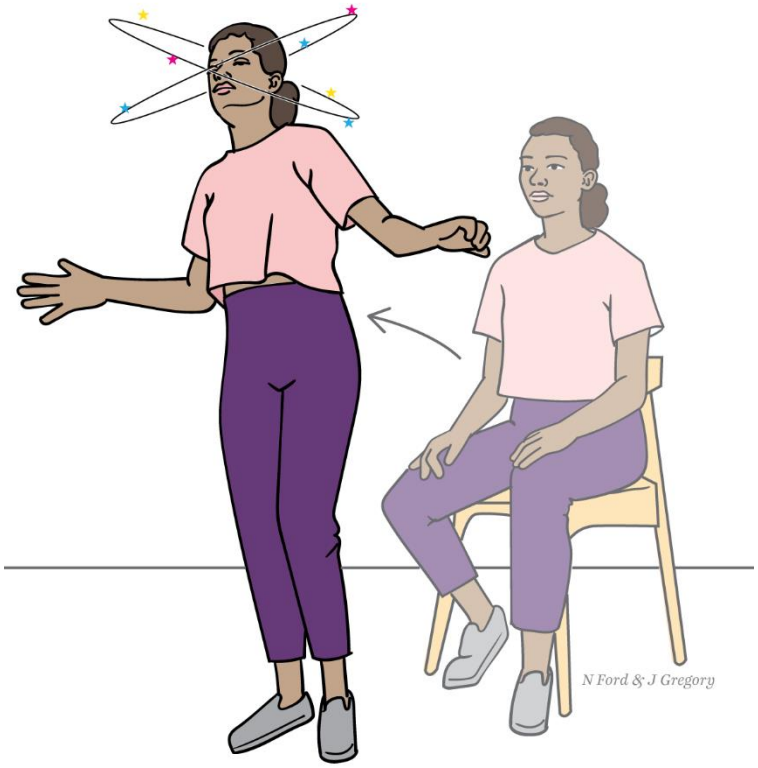
- You will need to work with the health care team including therapists and certified trainers to learn how to use one of these devices.
- There is a learning curve to use an EAW device. Some people learn to use the device quickly and others need more time.
- Learning how to stand and balance in the device takes approximately 1 to 2 sessions.
- Learning how to take steps with the device takes approximately 3 to 5 sessions.
- For use in the home, on average, people require 12 to 24 sessions.
- Each session may last from 30 minutes to 2 hours depending on stamina.
- Previous experience with standing exercises/standing frame use may help you to learn faster.
    - Certain limitations may limit how fast it takes you to learn to use the exoskeleton.
        - (See Chapter 9 for further information)

What to wear when using an exoskeleton?



- Exoskeletons are designed to be fitted over clothing.
- Sweatpants
- Athletic wear
- Elastic waist pants
- Avoid jeans, pants with zippers, pants with thick seams.
- You may require compression stockings.
- ReWalk and Indego use a footplate that is inside your shoes, therefore, you may need wide or extra wide shoes with enough room to accommodate your foot and the footplate.
    - You and your therapist will work together to find the correct shoe size.
- Ekso requires a supportive shoe to accommodate your weight when standing.
    - Your feet are placed on external footplates in the Ekso device.

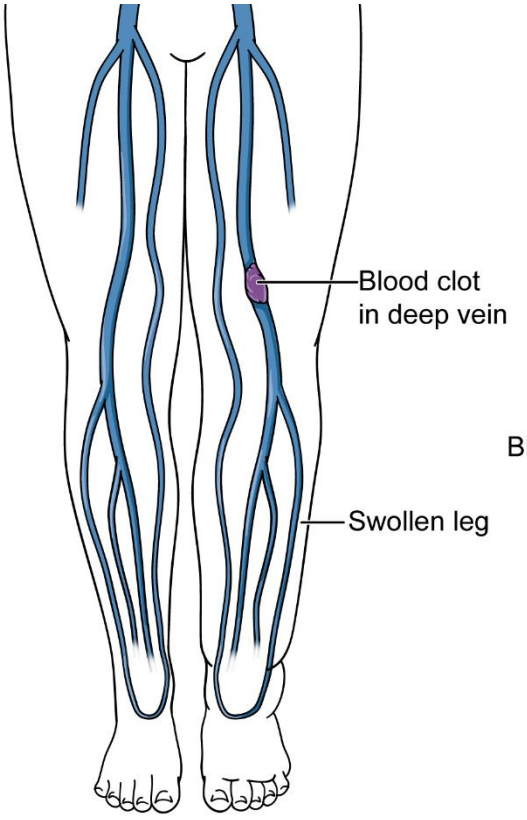
What would prevent me from using an exoskeleton?

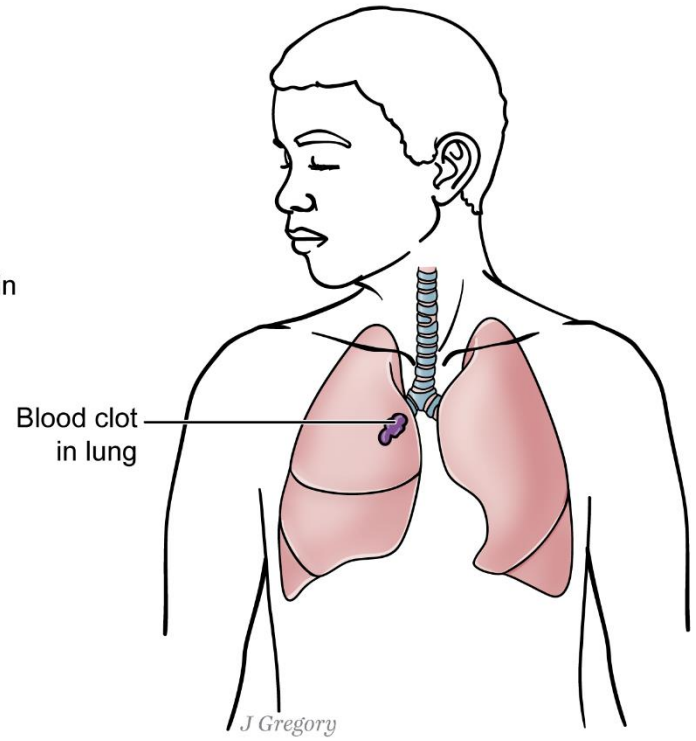


- Learning to use an exoskeleton to help walk requires a moderate to high level of physical activity and effort.
- If you have heart disease, lung disease or a chronic medical condition please notify your healthcare provider.
- Some limitations that may limit use of exoskeletons include:
  - Limited ROM of feet, knees and/or hips
  - Trunk control
  - Uneven leg lengths
  - Standing Balance
  - Spasticity
  - Stamina and coordination
  - Motivation
  - Ability to maintain stable blood pressure when going from sitting to standing
  - Ability to clearly understand and follow directions
- Blood Pressure

- Orthostatic hypotension is a sudden drop in blood pressure when transitioning from lying to sitting or sitting to standing.
- You may feel lightheaded, dizzy and/or faint.
- You can improve your blood pressure by using a tilt table or a standing frame to allow your body to adjust to being upright.
- Discuss with your health care team if medication is needed to help low blood pressure.
- There are wearable items to improve blood pressure which can include compression stockings and/or abdominal binders.

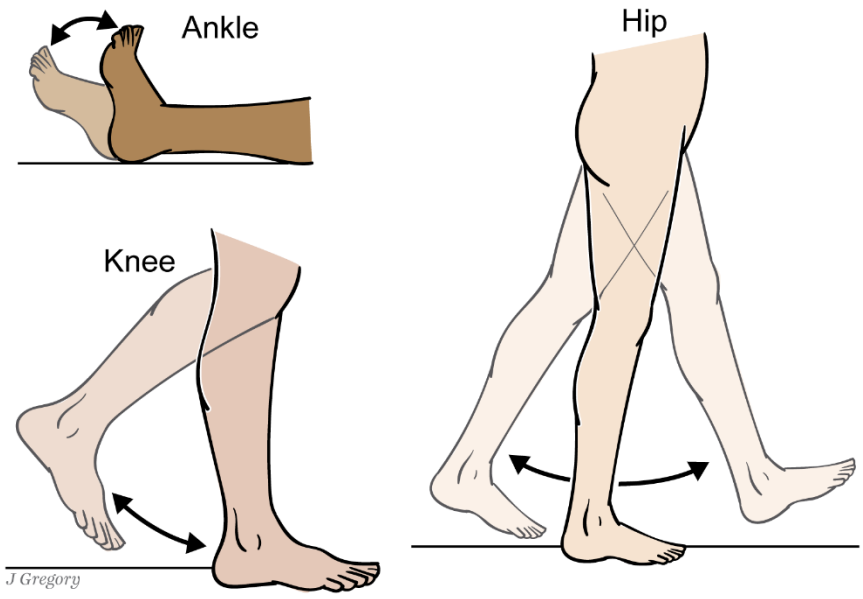
- Blood Clots
    - Blood clots in the legs or lungs require treatment with a blood thinner medication.
    - If you have swelling in your legs, you may need to undergo an ultrasound to check for clot before use of the exoskeleton.
    - If you have a blood clot, you may still be able to use the exoskeleton if it is being treated appropriately.
        - However, the risk of bleeding after a fall may be significantly increased.
    - Please discuss with your medical provider if use of the EAW is still appropriate while on a blood thinner medication.
    - For further information regarding blood clots in spinal cord injury please visit:
        - https://pva.org/wp-content/uploads/2021/09/consumerguide_bloodclots_august2019_1.pdf



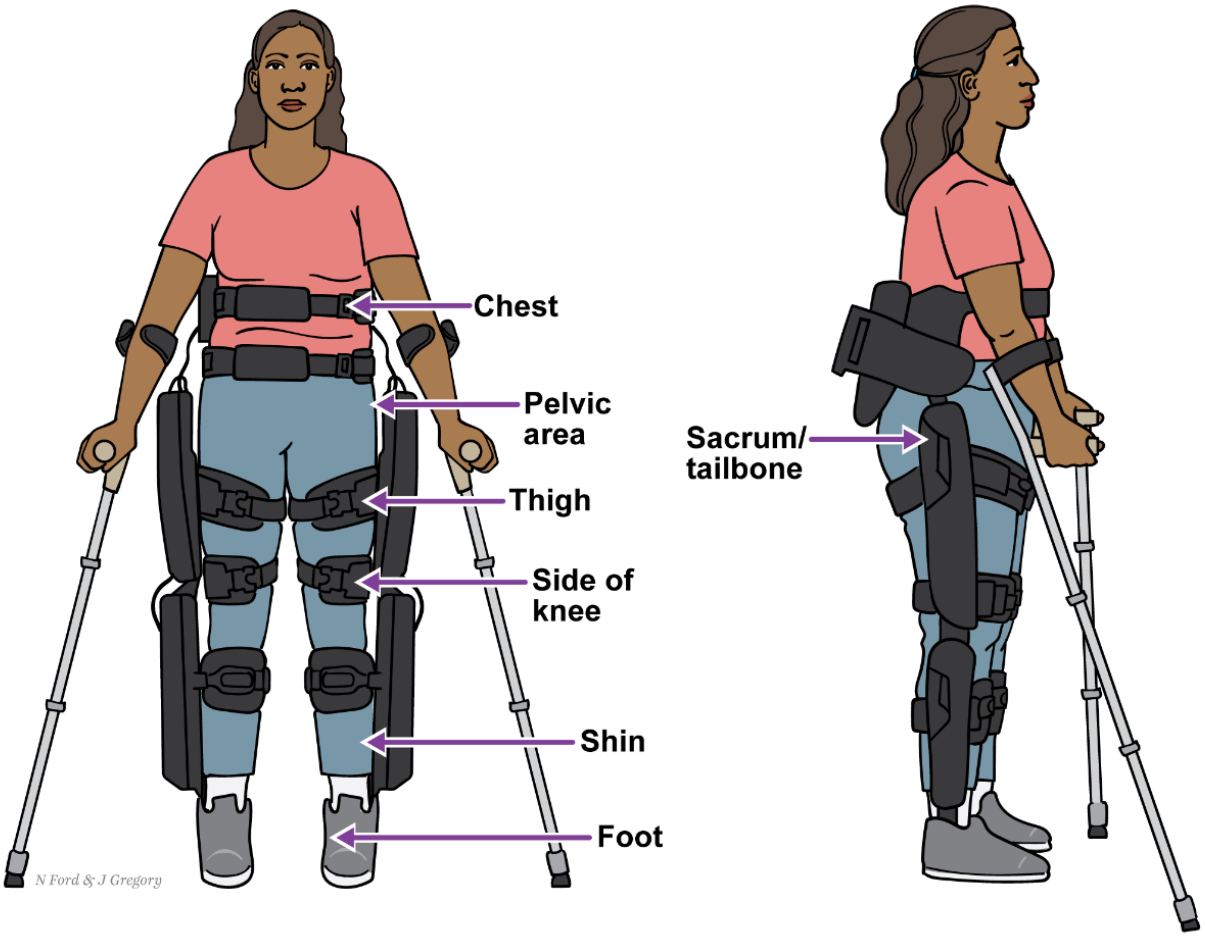


- Spasticity
    - Spasticity is a muscle spasm not under your conscious control.
    - Moderate to severe spasticity will prevent use of an EAW device by preventing proper fitting or interfering with the walking action.
    - Therapies available to reduce spasticity include stretching exercises, medications by mouth such as baclofen and tizanidine, baclofen pump, and/or botulinum (“Botox”) injections. Discuss with your medical provider treatment options.

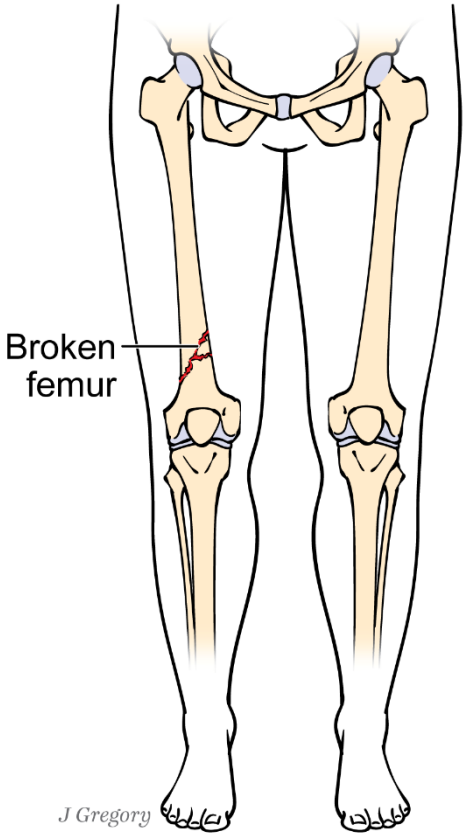
- Range of motion
    - You will need adequate motion of the shoulders and arms for use and placement of crutches or walker as well as adequate range of motion of the hips, knees, ankles, and feet to properly be fitted for an EAW device. **(See Figure below)**
    - Please discuss with your physician or physical therapist regarding what range of motion requirements are needed for EAW device use.
        - **For more details, please see Appendix A**



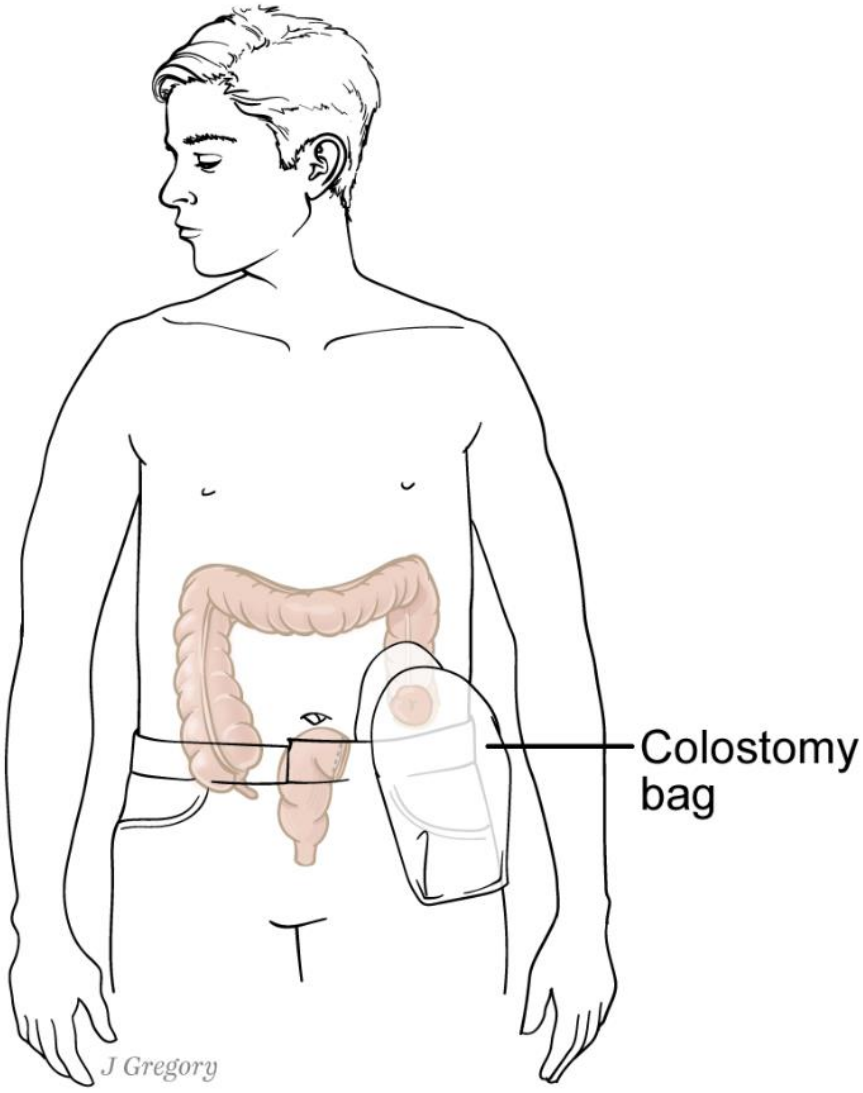
- Wounds
    - Pressure injuries or open wounds can prevent the use of an exoskeleton.
    - Wounds cannot be on a contact point with the exoskeleton device **(See Figure Below)**.
    - Most common locations of pressure wounds are sacrum/tailbone, the outside of the hip, and knees.
    - These are the critical points of contact to strap the device with your body and therefore any wounds to those areas would be worsened.
    - For further information regarding pressure injuries please visit:
        - https://pva.org/wp-content/uploads/2021/09/consumer-guide_pressure-ulcers.pdf



- Osteoporosis/Fracture
    - Osteoporosis is low bone density with structural bone deterioration that increases the risk of fractures.
    - Fragility fractures are caused by situations/activities/movements that would not ordinarily result in fracture. (Ex: Stretching, low height falls, lifting a leg, rotating hips)
    - People with SCI can lose significant amount of bone density due to paralysis and non-weight bearing status and are at increased risk of osteoporosis and fragility fractures.
    - If you have osteoporosis or unhealed fractures, you should speak with a medical provider prior to usage.
    - For further information regarding bone health and osteoporosis management in spinal cord injury please visit:
        - https://pva.org/wp-content/uploads/2022/05/CPG_Spinal-Cord-Medicine_2022_FINAL.pdf



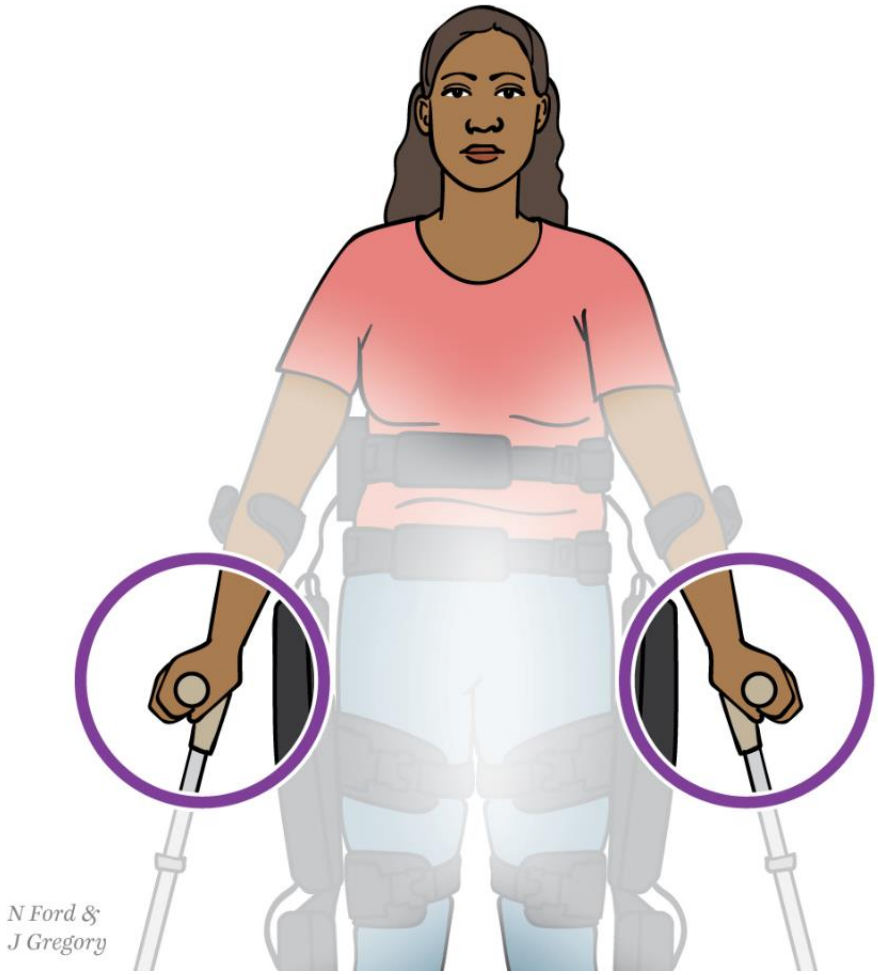
- Colostomy
    - A colostomy bag does not prevent the use of an exoskeleton device. Using a colostomy bag will depend on the brand of exoskeleton and points of contact with the device.



- Pregnancy
    - An exoskeleton device cannot be used during pregnancy.
    - This is due to the risk of fall and the inability to fit into the device as pregnancy progresses.
    - For further information regarding pregnancy in spinal cord injury please visit:
        - https://pva.org/wp-content/uploads/2021/09/sexuality-consumer-cpg-2012.pdf

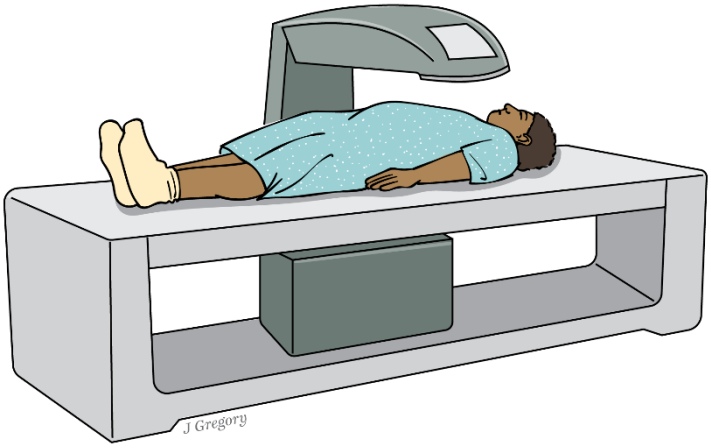
- Arm and hand function

- Most exoskeletons require some degree of arm and hand function to hold and use crutches or a walker.
- For further information regarding arm and hand function in spinal cord injury, please visit:
  - https://pva.org/wp-content/uploads/2021/09/consumer-guide_upper_limb.pdf



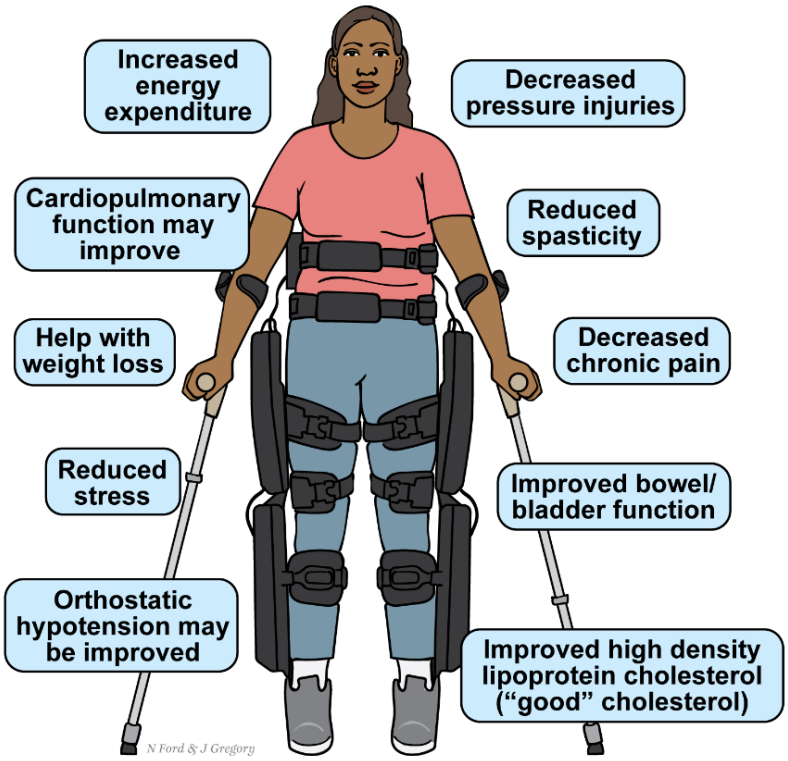
What kind of tests may I need before using an exoskeleton?

- You should have a physical exam by your medical provider to determine your general health.
- You will also need to have a range of motion and spasticity examinations.
- For additional requirements that can assist your physician please see Appendix B
- Additional imaging studies may be useful or required by your physician:
    - Bone health / osteoporosis
        - One way to evaluate bone health is using a Dual energy x-ray absorptiometry scan [DEXA] scan which is a non-invasive test used to measure bone density and assess the risk for osteoporosis or fracture.



    - Deep Vein Thrombosis
        - Ultrasound of legs can determine if you have a blood clot in your legs.

Why would I want to use an exoskeleton?



- Allowing wheelchair users to stand and walk may have multiple benefits on a person's physical and emotional health.
    - Of note, not everyone has these benefits.
- Medical benefits are similar to those seen with any regular exercise or physical activity and may include:
    - Improved bowel/bladder function
    - Improved core strength resulting in improved reaching while seated
    - Decreased chronic pain
    - Reduced spasticity
    - Decreased pressure injuries
    - Reduced stress
    - Increased energy expenditure
    - Help with weight loss
    - Cardiopulmonary function may improve with regular use of the exoskeleton

    - Improved high density lipoprotein cholesterol (HDL-c, the “good” cholesterol)
    - Orthostatic hypotension may be improved with regular use the use of exoskeleton
- Other benefits include from improved trunk stability include:
    - Increased wheelchair independence
    - Increased community mobility
    - Increased social participation

What are the limitations of an exoskeleton?

- An exoskeleton is not a fix for paralysis but aids with movement of the legs.
- One of the biggest drawbacks of exoskeletons is the high cost.
    - (Each exoskeleton costs around $100,000, which is why most are used in rehabilitation centers and for research purposes)
- Their weight is heavy, making them difficult to transport, however when using the device, the user does not feel the weight.
- They are intended for use to provide assisted walking which consists of providing some assistance from the device with a trained companion who supervises and adjusts the device in real time.
- Assisted walking will not provide independent functional walking which includes clearing obstacles, turning, and walking with variable cadence and speed.
- Even if you learn to walk without assistance, you will always need a companion, spotter, or trainer with you while walking in one of these devices.
    - This is because if you drop a crutch or fall, you will need assistance.
- Battery life is about 3-4 hours depending on intensity of use.

What are the risks of using an exoskeleton?

- Fragility fractures are a risk due to loss of bone density in legs and feet after SCI.
- Simply standing and stepping with your own weight bearing may cause a fragility fracture if your bones have lost too much bone density.
- Use of exoskeleton may trigger episodes of autonomic dysreflexia in some people based on level of injury.
- When using the exoskeleton you may experience a different response in sweating, heart rate and blood pressure.
- There is a risk of a fall that could result in an injury such as muscle soreness, sprained joint, cuts, bruising, head injury and/or bone fracture.

How do I get involved?

- Currently exoskeletons are used mostly for rehabilitation purposes, so please contact your health care team.
- Personal prescription of one of the FDA cleared devices for home use is possible through a trained healthcare provider.
    - You and your designated companion must pass certain eligibility criteria and only a trained provider can give approval for personal prescription of one of these EAW devices.
- Contact your healthcare team to see if you can get one for home use.
- If your healthcare provider is unfamiliar with exoskeletons, please contact the exoskeleton companies directly for assistance.
    - Ekso/Indego – https://eksobionics.com/contact/
        - Email: hello@eksobionics.com
        - Phone: +1 (510) 984-1761
    - ReWalk – https://rewalk.com/contact/
        - Email: contact@rewalk.com
        - Phone: +1(508) 251-1154

- You can also search ongoing clinical trial at **https://clinicaltrials.gov/** using "exoskeleton" as the keyword.
    - Results can then be filtered by condition, location, eligibility criteria and if actively recruiting.

Appendix A – Exoskeleton Details

	EksoNR and Ekso GT	Indego	ReWalk P6.0
Institutional Use	1. T4 to L5 (upper extremity motor function of at least 4/5 in both arms) 2. C7 to T3 (ASIA D with upper extremity motor function of at least 4/5 in both arms)	C7 to L5	T4 to T6
Personal Use	Not allowed	T3 to L5*	T7 to L5*
Companion/Trainer Required (Mandatory)	Yes		
Mobility Aids (Mandatory)	Walker, Crutches, Canes		
Range of Motion requirements	Hips: 135° flexion to 20° extension Knees: 130° flexion to 0° extension Ankles: 10° plantarflexion to 10° dorsiflexion	Hips: 110° flexion to 30° extension Knees: 110° flexion to 10° extension Ankles: <=5° contractures	Hips: 104° flexion to 34° extension Knees: 110° flexion to 2° extension Ankles: 5° plantarflexion; 20° dorsiflexion
Height requirements	5’2” – 6’2” (158 – 188 cm)	5'1" – 6'3" (155 – 191 cm)	5’3” – 6’2” (160 – 190 cm)
Max Weight requirements	220 lb (100kg)	250 lb (113 kg)	220 lb (100 kg)
Device Weight	50 lb (23 kg)	29 lb (13 kg)	66 lb (30 kg)
Variable Assistance	Yes	Yes	No
Surface types	Smooth, grass, cement, carpet, transitions, thresholds	Smooth, grass, cement, carpet, transitions, thresholds	Smooth, grass, cement, carpet, transitions, thresholds, curbs, stairs
Battery Life	1 hour of continuous usage per charge	1.5 hours of continuous usage per charge	3 hours of continuous usage per charge
Expected Useable Life	4 years	5 years	5 years

*Footnotes: See FDA approval or manufacturer for additional home use requirements

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Appendix B - Physician Checklist

- ❑ **1. Weigh less than 220 lb**
- ❑ **2. Adequate cardiopulmonary function to perform moderate to high level physical activity**
- ❑ **3. Normal range of motion of shoulders, hips, knees, and ankles**
- ❑ **4. Able to tolerate sitting/standing upright without lightheadedness, dizziness, and/or syncope**
- ❑ **5. Adequate hand function to use a walker or crutches**
- ❑ **6. Able to communicate with a trainer and follow directions**
- ❑ **7. No leg length discrepancy more than 0.5”**
- ❑ **8. No pressure injuries on the locations that contact the exoskeleton device**
- ❑ **9. No Pregnancy**
- ❑ **10. No Mechanical ventilation use**
- ❑ **11. No Blood Clots**
- ❑ **12. No Severe Spasticity (Modified Ashworth Scale ≥ 4)**
- ❑ **13. No severe osteoporosis or unhealed fractures of lower extremities**